



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/761,899

01/21/2004

Robert Allan Phillips

14450.0006US01

4223

23552 7590 08/04/2006

MERCHANT & GOULD PC
P.O. BOX 2903
MINNEAPOLIS, MN 55402-0903

EXAMINER

MULLEN, KRISTEN DROESCH

ART UNIT

PAPER NUMBER

3766

DATE MAILED: 08/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/761,899

Applicant(s)

PHILLIPS, ROBERT ALLAN

Examiner

Kristen Mullen

Art Unit

3766

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 1/7/05 (IDS).
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>1/7/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Specification

1. The abstract of the disclosure is objected to because it contains legal phraseology such as “comprising”. Correction is required. See MPEP § 608.01(b).

2. Applicant is reminded of the proper content of an abstract of the disclosure.

A patent abstract is a concise statement of the technical disclosure of the patent and should include that which is new in the art to which the invention pertains. If the patent is of a basic nature, the entire technical disclosure may be new in the art, and the abstract should be directed to the entire disclosure. If the patent is in the nature of an improvement in an old apparatus, process, product, or composition, the abstract should include the technical disclosure of the improvement. In certain patents, particularly those for compounds and compositions, wherein the process for making and/or the use thereof are not obvious, the abstract should set forth a process for making and/or use thereof. If the new technical disclosure involves modifications or alternatives, the abstract should mention by way of example the preferred modification or alternative.

The abstract should not refer to purported merits or speculative applications of the invention and should not compare the invention with the prior art.

Where applicable, the abstract should include the following:

- (1) if a machine or apparatus, its organization and operation;
- (2) if an article, its method of making;
- (3) if a chemical compound, its identity and use;
- (4) if a mixture, its ingredients;
- (5) if a process, the steps.

Extensive mechanical and design details of apparatus should not be given.

3. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The following title is suggested: METHOD OF DETERMINING CARDIAC OUTPUT BASED ON VALVE CROSS SECTIONAL AREA ESTIMATE.

4. The disclosure is objected to because of the following informalities: page 7, line 23 “F” should be changed to --of--.

Appropriate correction is required.

Drawings

5. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: 22, 24. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 101

6. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

7. Claims 1-7 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claimed invention is an abstract idea with no claimed practical application (although one is disclosed in the specification). An abstract idea can be included in the claimed invention, but the claimed invention must be a practical application that produces a useful, concrete and tangible result. In this case, a useful, concrete, tangible result is not produced by the claimed invention.

8. The examiner suggests amending the claims to replace the step of “utilizing” with a specific method step that produces the useful, concrete and tangible result of the cardiac output value of the patient or the valve diameters or valve cross sectional areas of the patient.

An example of a compliant amendment to claim 1:

A method of determining cardiac output of a patient, the method comprising the steps of:

- (a) measuring the patient’s height
- (b) estimating the heart valve diameter and cross sectional area of the heart valve based on the patient’s height
- (c) measuring the velocity time integral or stroke distance of blood flowing from the heart of the patient
- (c) calculating a value for the cardiac output of the patient as a product of the velocity time integral and the heart valve cross sectional area.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 1-7 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: the step of determining the cardiac output in association with the formula for aortic annular diameter based on patient height and the step of determining the cardiac output with the formula for pulmonary annular diameter based on patient height.

Art Unit: 3766

11. Claim 8 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite in that it fails to point out what is included or excluded by the claim language. This claim is an omnibus type claim.

Claim Objections

12. Claim 1 is objected to because of the following informalities:

- line 3, “patients” should be changed to --patient’s--
- line 5, “heat” should be changed to --heart--
- line 6, “measurement” should be changed to --measurements--.

13. Claim 5 is objected to because of the following informalities:

- lack of antecedent basis for the limitation "the formula" in line 2
- “determining a cross sectional” should be changed to --determine a cross sectional area--.

14. Claim 6 is objected to because of the following informalities:

- lack of antecedent basis for the limitation "the formula" in line 2
- “determining” should be changed to --determine--.

15. Claim 7 is objected to because of the following informalities:

- lack of antecedent basis for the limitation "the formula" in line 2
- “determining” should be changed to --determine--.

Appropriate correction is required.

16. Applicant is advised that should claim 6 be found allowable, claim 5 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight

Art Unit: 3766

difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 102

17. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

18. Claims 1, 4 and 8 rejected under 35 U.S.C. 102(b) as being anticipated by Burton et al. (5,052,395).

Burton shows a method comprising measuring a patient's height, measuring the velocity time integral or stroke distance of blood flowing from the heart and utilizing the two measurements to determine cardiac output and to determine the output of aortic annular (Col. 5, lines 1-8; Col. 17, line 59-Col. 18, line 29).

19. Claims 1, 4 and 8 rejected under 35 U.S.C. 102(b) as being anticipated by Barnes et al. (4,509,526).

Barnes shows a method comprising measuring a patient's height, measuring the velocity time integral or stroke distance of blood flowing from the heart and utilizing the two measurements to determine cardiac output and to determine the output of aortic annular (Col. 12, line 58-Col. 13, line 8; Abs. Col. 2, line 64- Col. 3, line 4)

Allowable Subject Matter

20. Claims 2-3 and 5-7 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 101 and 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Conclusion

21. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

- Stevens et al. (4,858,614) and Huntsman et al. (4,796,634) each show utilizing the patients height to approximate the patient's aorta diameter and using the approximated diameter in calculating the cardiac output. Neither reference discusses approximating the aortic valve or annular diameter based on the patient's height.
- Muhlenberg et al. (2003/019979) utilizes a measurement of the outflow tract diameter and the velocity integral to calculate cardiac output.
- Finkelstein et al. (5,241,966) shows determining the cardiac output based on body surface area which is derived from the height of a patient
- Seitz et al. (2003/0195409) shows calculating the aortic and pulmonary valve cross sectional areas as a function of stroke volume or cardiac output. Seitz does not utilize height in the calculation of the valve cross sectional area.
- Osypka et al. (2003/0163056) shows calculating the stroke volume based on the velocity integral and the aortic valve cross sectional area. Osypka does not show that the aortic valve cross sectional area is calculated as a function of the patient's height.

Art Unit: 3766

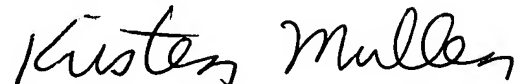
22. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kristen Mullen whose telephone number is (571) 272-4944. The examiner can normally be reached on M-F, 10:30 am-6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on (571) 272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Kristen Mullen
Patent Examiner
Art Unit 3766

kdm

A handwritten signature in black ink that reads "Kristen Mullen". The signature is written in a cursive, flowing style.